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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Lehman *et al.*

Serial No.: 09/821,139

Group Art Unit: 1616

Filed: March 29, 2001

Examiner: Haghighatian, M.

For: NASAL ADMINISTRATION OF
AGENTS FOR THE TREATMENT OF
GASTROPARESIS

Attorney Docket No.: 7960-131

Confirmation No.: 5628

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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.

1b. A legible copy of:

- ☒ Each U.S. patent application publication and U.S. and foreign patent;
- ☒ Each publication or that portion which caused it to be listed on the PTO-1449;
- ☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;

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☐ all other information or portion which caused it to be listed on the PTO-1449.

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1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.

- 1d. ☒ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
 - ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
 - ☐ Before the mailing of the first Office action on the merits;
 - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

(Check either Item 3a or 3b)

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☒ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
 - ☒ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

(Item 3b to be checked if any reference known for more than 3 months)

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement *(applicable if Item 3a or Item 4 is checked)*

(Check either Item 5a or 5b)

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a

communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

- 5b. ☐ In accordance with 37 C.F.R. §1.97(e)(2), it is certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was known by any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

(Check appropriate Items 6a, 6b and/or 6c)

- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. __, filed on __, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. __, filed on __, and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. *(Check either Item 7a or 7b)*
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on __. A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on __.
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:

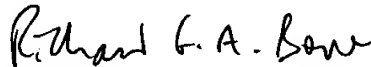
(Check Item 8a, 8b, or 8c)

- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.

9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date October 15, 2002



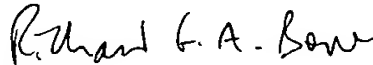
Richard G. A. Bone (Reg. No.)
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(Copy of Certificate Enclosed)

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9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150.
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Respectfully submitted,

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LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	ATTY. DOCKET NO.	SERIAL NO.
	7960-131	09/821,139
	APPLICANT	
	Lehman <i>et al.</i>	
	FILING DATE	GROUP
	March 29, 2001	1616

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AJ	5,576,317	11/19/1996	Gonsalves			
	AK	4,729,997	3/8/88	Wenig			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AL	HU 210115 B	2/28/95	Hungary (with English abstract)				X


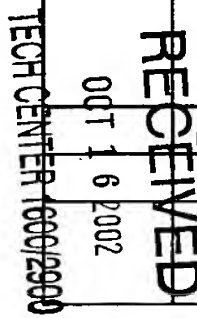
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AM	Bateman, et al., 1980 "The Pharmacokinetics Of Metoclopramide In Man With Observations In The Dog," Br. J. Clin. Pharmac. 9:371-377.
	AN	Chiara, et al., 1995 "Prevention of Delayed Emesis with Metoclopramide and Dexamethasone in Patients Receiving Moderately Emetogenic Cytotoxic Treatment," Anticancer Research 15:1597-1599.
	AO	Clark, et al., 1986, "Antiemetic (AE) trials to control delayed vomiting (V) following high-dose cisplatin (DDP)", <i>Proceedings of ASCO</i> 5:257, abstr. 1005.
	AP	Clark, et al., 1993 "Delayed emesis: A dilemma in antiemetic control", Support Care Cancer 1:182-185.
	AQ	Cubeddu, et al., 1993, "Participation of serotonin on early and delayed emesis induced by initial and subsequent cycles of cisplatin-based chemotherapy: Effects of antiemetics", <i>J. Clin. Pharmacol.</i> 33:691-697.
	AR	De Mulder, et al., 1990, "Ondansetron compared with high-dose metoclopramide in prophylaxis of acute and delayed cisplatin-induced nausea and vomiting", <i>Ann. of Internal Med.</i> 113:834-840.
	AS	Du Bois, et al., 1995, "Cisplatin-induced alterations of serotonin metabolism in patients with or without emesis following chemotherapy", <i>Oncol. Rep.</i> 2:839-842.
	AT	Gandara, 1991, "Progress in the control of acute and delayed emesis induced by cisplatin", <i>Eur. J. Cancer</i> 27:S9-S11.
	AU	Gandara, et al., 1992, "The delayed-emesis syndrome from cisplatin: Phase III evaluation of ondansetron versus placebo", <i>Semin. Oncol.</i> 19:67-71.

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DATE CONSIDERED

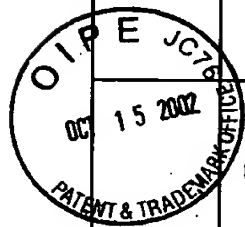
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

	AV	Gralla, et al., "Management of Chemotherapy-induced Nausea and Vomiting" http://www.cancernetwork.com/home/nausea.htm Last viewed 10/11/02
	AW	Gralla, et al., 1987, "The management of Chemotherapy-induced Nausea and Vomiting", <i>Medical Clinics of North America (Cancer Pain)</i> 71:289-301
	AX	Grunberg, et al., 1988, "Oral metoclopramide with or without diphenhydramine: Potential for prevention of late nausea and vomiting induced by cisplatin", <i>J. of the Natl. Cancer. Inst.</i> 80:864-868.
	AY	Jones, et al., 1991, "Comparison of dexamethasone and ondansetron in the prophylaxis of emesis induced by moderately emetogenic chemotherapy", <i>Lancet</i> 338:483-486.
	AZ	Kris et al., 1989, "Controlling delayed vomiting: Double-blind, randomized trial comparing placebo, dexamethasone alone, and metoclopramide plus dexamethasone in patients receiving cisplatin", <i>J. of Clin. Oncol.</i> 7:108-114.
	BA	Kris, et al., 1992, "Oral ondansetron for the control of delayed emesis after cisplatin", <i>Cancer Suppl.</i> 70:1012-1016.
	BB	Lee, et al., 1994, "Ondansetron compared with ondansetron plus metoclopramide in the prevention of cisplatin-induced emesis", <i>J. of Korean Med. Sci.</i> 9:369-375.
	BC	Levitt, et al., 1993, "Ondansetron compared with dexamethasone and metoclopramide as antiemetics in the chemotherapy of breast cancer with cyclophosphamide, methotrexate, and fluorouracil", <i>New England J. of Med.</i> 328:1081-1084.
	BD	Li, et al., 1991, "Control of cisplatin-induced delayed emesis", <i>Chin. Med. J. (Taipei)</i> 48:451-455. (With English abstract)
	BE	Locatelli, et al., 1995 "Tolerability and Safety of Nasally Administered Metoclopramide (MCP) for the Prevention of CIS-Platinum (CDDP) Induced Delayed Emesis", <i>Proceedings of ASCO</i> Vol: 14 March 1995, abstr. 1759.
	BF	Madej, et al., 1994, "A report comparing the use of tropisetron (Navoban), a 5-HT ₃ antagonist, with a standard antiemetic regimen of dexamethasone and metoclopramide in cisplatin-treated patients under conditions of severe emesis", <i>Semin. Oncol.</i> 21:3-6.
	BG	Medical Economics Co., 1999, PDR 53th Edition 1999, "Physician's Desk Reference" 2643-2545
	BH	Medical Economics Co., 2000, PDR 54th Edition 2000, "Physician's Desk Reference" 2603-2605
	BI	Moreno, et al., 1992, "Comparison of three protracted antiemetic regimens for the control of delayed emesis in cisplatin-treated patients", <i>Eur. J. Cancer</i> 28:1344-1347.

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	BJ	Navari, et al., 1995, "Oral ondansetron for the control of cisplatin-induced delayed emesis: A large, multicenter, double-blind, randomized comparative trial of ondansetron versus placebo", <i>J. of Clin. Oncol.</i> 13 :2408-2416.
	BK	Nino, et al., 1987, "A randomized controlled trial of acute and delayed cisplatin-induced emesis with metoclopramide, dexamethasone and prochlorperazine", <i>Jpn. J. Cancer Chemother.</i> 14 :2881-2884. (With English summary)
	BL	O'Brien, et al., 1989, "The role of metoclopramide in acute and delayed chemotherapy induced emesis: A randomized double blind trial", <i>Br. J. Cancer</i> 60 :759-763.
	BM	Ogawa, 1982, "Metoclopramide as an antiemetic in chemotherapy", <i>New Eng. J. of Med. Correspond.</i> 307 :249-250.
	BN	Roila, et al., 1994 "Cisplatin-induced delayed emesis: Pattern and prognostic factors during three subsequent cycles," <i>Annals of Oncology</i> 5 :585-589.
	BO	Roila, et al., 1991, "Predictive factors of delayed emesis in cisplatin-treated patients and antiemetic activity and tolerability of metoclopramide or dexamethasone", <i>Am. J. Clin. Oncol. (CCT)</i> 14 :238-242.
	BP	Scaglione, et al., 1993, "Pharmacokinetics and bioavailability of metoclopramide nasal spray versus metoclopramide intravenous in healthy volunteers and cancer patients", <i>Arzneim.-Forsch./Drug Res.</i> 43 :986-988.
	BQ	Shinkai, et al., 1989 "Control of Cisplatin-induced Delayed Emesis with Metoclopramide and Dexamethasone: a Randomized Controlled Trial," <i>Jpn. J. Clin. Oncol.</i> 19 :40-44.
	BR	Soukop, et al., 1992, "Ondansetron compared with metoclopramide in the control of emesis and quality of life during repeated chemotherapy for breast cancer", <i>Oncol.</i> 49 :295-304.
	BS	Strum, et al., 1985, "Management of cisplatin(DDP)-induced delayed-onset nausea(N) and vomiting(V): Preliminary results with 2 drug regimens", <i>Proceedings of ASCO</i> 4 :263, abstr. C-1024.
	BT	Taylor, et al., 1986 "Oral Bioavailability of High-Dose Metoclopramide," <i>Eur. J. Clin. Pharmacol.</i> 31 :41-44.
	BU	Tomirotti, et al., 1994 "Efficacy and tolerability of nasally administered compared to parenterally administered metoclopramide in the symptomatic treatment of chemotherapy-induced emesis in cancer outpatients," <i>Support Care Cancer</i> 2 :389-392.
	BV	Vogt. et al., 1993 "Oral Medium-Dosed Metoclopramide versus Placebo as Highly Effective Antiemetic Prophylaxis in In- and Outpatients on Noncisplatin Chemotherapy," <i>Oncology</i> 50 :81-85.

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